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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/476,490	12/30/1999	LINDSAY S. MACHAN	110129.411	7911

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EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/476,490

Applicant(s)

MACHAN ET AL. *CM*

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15. 6) ☐ Other:

DETAILED ACTION

Oath/Declaration

1. The oath or declaration filed on 6/19/2000 is acknowledged and accepted.

Response to Arguments

2. Applicant's arguments with respect to claims 1-3, 9, 12-20, 30, 31 and 33 have been considered but are moot in view of the new ground(s) of rejection as follow.

Election/Restrictions

3. After careful reconsideration of this application, the species appear to be obvious variants because disclosed adhesion inducing-agents are known in the art for promoting adhesion. Therefore the species restriction in Paper No. 8 is withdrawn. Accordingly, claims 1-20 and 30-36 are currently pending and considered in this office action.

Claim Objections

4. Claim 7 is objected to because of the following informalities: The "," before and after "or" should be removed. Appropriate correction is required.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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6. Claims 1-20, 30, 31 and 33-36 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20, 30, 31 and 33-36 of copending Application No. 09/859,899. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 32 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of copending Application No. 09/859,899. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both direct to the method step of coating a stent graft with an agent which induces adhesion of the stent graft to vessel walls and a polymer being included in the coating.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-17 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume et al. (5,723,004) in view of Clapper (5,744,515). Dereume et al. disclose an vascular graft including a tubular braided stent (22) within porous graft layers (23, 24), the porous of the graft encourage tissue growth there into in order to assist in non-rejecting securing into place, the surface of the graft can be treated with drugs (col. 10, line 19 to col. 11, line 2) and wherein the vascular graft is bifurcated graft having tube and cylindrical configurations and can be self-expanding (col. 4, line 10-24, col. 5, lines 31-46), or balloon expanding (col. 8, lines 20-67). Although, Dereume et al. fail to disclose the stent graft releasing an agent which induces the *in vivo* adhesion of the stent graft to vessel wall, attention is directed to the Clapper reference which discloses adhesive materials promoting endothelialization for coating on implants such as vascular grafts in order to promote the attachment between the vascular grafts and the vessel wall (col. 7, lines 25 to col. 13, line 54), the adhesive materials including fibronectin, other adhesion molecules (col. 9, line 29 to col. 10, line 46). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an adhesive material as disclosed by Clapper such as fibronectin

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into the vascular graft of Dereume et al. in order to promote the attachment between the stent graft and wall vessels.

In regard to claims 4, 5, 7, 8, 10, 34, 35 and 36, although, the teaching of Dereume et al. in view of Clapper fails to disclose the stent graft releasing adhesive agents such as silica; a component of extracellular matrix; polylysine or ethylenevinylacetate; growth factor, cytokines; and cyanoacrylate, all of these agents are known in the art that can be used to promote the adhesion between tissues or tissues and implants. For example:

Ken (6,113,629) discloses a list of proteins that support cells growth, including fibronectin, gelatin, collagen, fibrin and others and inorganic adhesive gels such as silica, cyanoacrylates, gelatin and others for promoting the adhesion (col. 3, line 14 to col. 4, line 9). Cahalan et al. (5,607,475) discloses a list of cell attachment proteins, including fibronectin, vitronectin, laminin, growth factors/cytokines and others (col. 6, lines 4-24).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the vascular graft of Dereume et al. in view of Clapper by having the vascular graft releasing a component of extracellular matrix, polylysine, ethylenevinylacetate, growth factor, cytokines, and/or silica and cyanoacrylate. Doing so would amount to mere substitution of one material for another within the same art that would perform equally well in the vascular graft of Dereume et al. in view of Clapper.

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To substitute a well known material based on its suitability for the intended use without special functional significance are not patentable, in re Hotchkiss v. Greenwood, 52 USPQ 248.

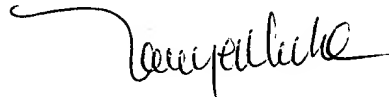
10. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume et al. '004 in view of Clapper '515 further in view of Yamamoto et al. (5,948,427). The teaching of Dereume et al. in view of Clapper disclose all the limitations of the claims (see paragraph above) except for a presence of a coating which delays the onset of adhesion or fibrosis. Yamamoto et al. disclose in order to prevent adhesion at an undesired site, surgical adhesive materials can be inactive by providing an impermeable outer coat and the surgical adhesive materials can be activated at a desired site by rupturing the impermeable outer coat (col. 2, line 51 col. 6, line 51 and col. 10, claims 1-17). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an outer coat that delays the *in vivo* adhesion into the vascular graft of Dereume et al. in view of Clapper in order to prevent adhesion between the graft and vessel walls at an undesired site.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho
Patent Examiner
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April 21, 2003